2.3. 510(K) Summary of Safety and Effectiveness

OCT 2 2 2002

Submitter:

VSM MedTech Ltd.
15th Floor, 675 West Hastings Street
Vancouver, BC V6B 1N2 CANADA

Company Contact:

Daryl Wisdahl
Director of Regulatory Affairs and Clinical Research
Phone: (604) 738-8763
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Regulatory Identification:

Device Name: BpTRU™ Portable Automated Non-Invasive Blood Pressure Monitor

Model Name: BPM-200

Device Classification Name: System, measurement, blood-pressure, non-invasive

Device Class: II

Regulation Numbers: CFR 870.1130

Panel: Circulatory System Device Panel (74)

Product Code: DXN

Classification Advisory Committee: Cardiovascular

Establishment Registration Number (Owner/Operator): 9034609

Predicate Device Information:

VSM Technology BpTRU™ Automated Non-Invasive Blood Pressure Monitor (Model BPM-100) as cleared by K994423, K002046 and K012636.

Device Description:

The BpTRU Portable Automated Non-Invasive Blood Pressure Monitor (Model BPM-200) is a portable automated, non-invasive blood pressure monitor designed to measure the blood pressure and pulse rate of patients using an upper arm cuff. The device uses a standard blood pressure cuff to measure the blood pressure in the upper arm. The device automatically inflates and deflates the cuff, and uses the oscillometric technique to calculate systolic and diastolic blood pressure.

The BPM-200 has two blood pressure operational modes: Manual and Automatic. Manual Mode is designed to take a single blood pressure measurement. Automatic Mode takes six measurements, discards the first, and displays the average of the last five readings. The cycle time, or minutes between measurements (from the start of one measurement to the start of the next measurement), can be selected in Automatic Mode. Individual readings are stored and can be reviewed in both Manual and Automatic Modes.

The BPM-200 can be operated while mounted to a wall, attached to a roll-stand or self-standing on the tabletop. The new device includes an internal rechargeable battery and features USB connectivity.

Description of Modification:

The BPM-200 is an extension of the BpTRU family of NIBP devices, and as such the existing BPM-100 has been modified to create the BPM-200. The modifications include the addition of battery operation, USB connectivity, and provisions for pole-mounted and self-standing operation.

Indications for Use:

The BpTRU:

- Measures systolic and diastolic blood pressure and pulse rate in subjects 3 years of age or older
- Is intended for use in physicians' offices, nursing units, and patient care areas of hospitals.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 2002

VSM MedTech Ltd.
c/o Mr. Daryl Wisdahl
Director of Regulatory Affairs and Clinical Research
15th Floor, 675 West Hastings Street
Vancouver, BC V6B 1N2
CANADA

Re: K023055
Trade Name: BpTRU™ Portable Automated Non-Invasive Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: October 10, 2002
Received: October 11, 2002

Dear Mr. Wisdahl:

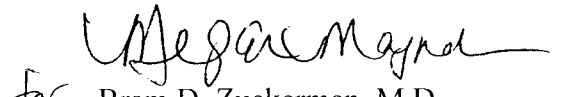
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.2. Indications for Use Statement

510(k) Number: K02-3055

Device Name: BpTRU™ Portable Automated Non-Invasive Blood Pressure Monitor

Model Name: BPM-200

Indications For Use:

The BpTRU BPM-200:

- Measures systolic and diastolic blood pressure and pulse rate in subjects 3 years of age or older.
- Is intended for use in physicians' offices, nursing units, and patient care areas of hospitals.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use **OR** **Over-The-Counter USE**

(Per 21 CFR 801.109) (Optional Format 1-2-96)

✓

for BDZ

Division of Cardiovascular & Respiratory Devices

510(k) Number K023055